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**STERILMED, INC.**

Medical Device Reprocessing  
Suture, Endo & Instrument Repair

**510(K) PREMARKET NOTIFICATION SUBMISSION**

MARCH 30, 2007

For Reprocessed Autosuture GIA Endoscopic Staplers

**II. SUMMARY AND CERTIFICATION**

OCT 18 2007

**A. 510(k) Summary**

**Submitter:** SterilMed, Inc.  
**Contact Person:** Caroline Butterfield  
11400 73<sup>rd</sup> Avenue North  
Maple Grove, MN 55369  
Ph: 888-856-4870  
Fax: 763-488-3350

**Date Prepared:** March 30, 2007  
**Trade Name:** Reprocessed AutoSuture GIA Endoscopic Staplers  
**Classification Name:** Staple, Implantable  
**Classification Number:** Class II, 21 CFR 878.4750  
**Product Code:** NLL

<b>Predicate Devices:</b>	The reprocessed AutoSuture GIA Endoscopic Staplers are substantially equivalent to the AutoSuture GIA Endoscopic Stapler (K061095).
<b>Device Description:</b>	SterilMed's reprocessed AutoSuture GIA Endoscopic Stapler places two triple staggered rows of titanium staples and the blade, contained in the reload, simultaneously divides the tissue between the two rows. These devices allow for a maximum of 8 reloads in a single surgical procedure. The OEM has specified that the subject staplers may be fired up to 25 times in a single surgical procedure. SterilMed has lowered the number of firings allowed to 8 based upon clinical input, the procedures these devices are used for and the maximum allowable firings for similar devices of other manufacturers.  Note: Only the stapler is the subject of this submission, the implantable staple and the staple cartridge are not reprocessed and therefore are not included.
<b>Intended Use:</b>	The reprocessed reloadable AutoSuture GIA staplers are intended to be used in abdominal, gynecologic, pediatric and thoracic surgery for the resection, transection of tissue and for anastomosis. In addition the AutoSuture ENDO GIA Staplers may be used for transaction and resection of liver tissue, hepatic vasculature and biliary structures.
<b>Functional and Safety Testing:</b>	Representative samples of reprocessed staplers are tested to demonstrate appropriate functional characteristics. Process validation testing is performed to validate the cleaning and sterilization procedures as well as device packaging. In addition, the manufacturing process includes visual and validated functional testing of all products produced.
<b>Conclusion:</b>	The reprocessed endoscopic staplers are substantially equivalent to the GIA Endoscopic Stapler (K061095) manufactured by AutoSuture.  This conclusion is based upon the devices' similarities in functional design (principle of operation), materials, indications for use and methods of construction.



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SterilMed, Inc.  
% Mr. Dennis J. Toussaint  
Director, Regulatory Affairs  
11400 73<sup>rd</sup> Avenue North, Suite 100  
Maple Grove, Minnesota 55369

OCT 18 2007

Re: K070930

Trade/Device Name: Reprocessed AutoSuture GIA Endoscopic Staplers  
Regulation Number: 21 CFR 878.4750  
Regulation Name: Implantable staple  
Regulatory Class: II  
Product Code: NLL  
Dated: October 10, 2007  
Received: October 11, 2007

Dear Mr. Toussaint:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

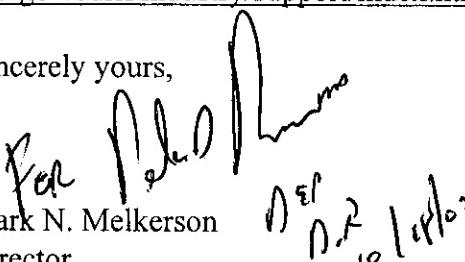
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Dennis J. Toussaint

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

  
Mark N. Melkerson  
Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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List of Devices Included in this Submission

OEM	Model	Description	Reprocessor	SterilMed Part Number
AutoSuture	030403	GIA Universal 12mm dia., 63 mm long shaft	SterilMed, Inc.	AUTO30403
	030449	Endo GIA Universal 12mm dia., 155 mm long shaft		AUTO30449
	EGIAUNIVXL	Endo GIA Universal XL – Long 12 mm dia., 255mm long shaft		AUTEGIAUNIVXL

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**STERILMED, INC.**  
Medical Device Reprocessing  
Small Equipment & Instrument Repair

510(K) PREMARKET NOTIFICATION SUBMISSION

MARCH 30, 2007

For Reprocessed AutoSuture GIA Endoscopic Staplers

## Indications for Use

510(k) Number (if known):

Device Name: Reprocessed AutoSuture GIA Endoscopic Staplers

### Indications For Use:

The Reprocessed Reloadable AutoSuture GIA staplers are intended to be used in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection of tissue and anastomosis. In addition the AutoSuture ENDO GIA Staplers may be used for transection and resection of liver tissue, hepatic vasculature and biliary structures.

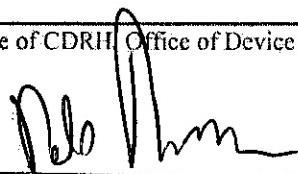
Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

  
**(Division Sign)**  
**Division of General, Restorative,  
and Neurological Devices**

510(k) Number 1L 070930